



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-697/S-012, S-013, S-014, S-015

Bracco Diagnostics
Attention: Melanie Benson, M.S., R.A.C.
Director, US Regulatory Affairs
P.O. Box 5225
Princeton, New Jersey 08543-5225

Dear Ms. Benson:

Please refer to your supplemental new drug applications dated August 28, 2002, received August 30, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kinevac[®] (sincalide) for Injection 5 mcg/vial.

We acknowledge receipt of your submissions dated October 3, October 21, October 23, November 1, November 4, November 8, and November 20, 2002.

These supplemental new drug applications provide for the following:

1. Supplement-012 provides for the change in the manufacturing site for the drug product.
2. Supplement-013 provides for the change in the formulation for the drug product.
3. Supplement-014 provides for the change in the packaging for the drug product.
4. Supplement-015 provides for the change in the testing for the drug product.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the submitted labeling text.

The final printed labeling (FPL) must be identical to the labeling package insert, vial label, and shipper label submitted August 28, October 3, and as amended on November 4, 2002.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 10 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 17-697/S-012, S-013, S-014, S-015." Approval of these submissions by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitments in your submissions dated November 8, 2002 and November 20, 2002.

These commitments are listed below:

1. To set specifications for impurities at the conclusion of the two-year stability study. The proposed specifications will be submitted as a prior approval supplement by March 2005.
2. To test the three validation batches (initial timepoint) and the three stability batches (18-month timepoint) by both (b)(4)----- to provide comparative data. The results of these comparative studies will----- in January 2003 as a prior approval supplement.
3. To work with (b)(4)-----to reduce (or eliminate) the (b)(4)-----
The status and results will be reported in Annual Reports (July), with the final results being reported in the July 2004 Annual Report.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Although, not approvability issues, we have the following comment and recommendation.

In the draft labeling, you have removed the periods after the N and J in N.J. to read as NJ except in the draft shipper label. For consistency, consider making this editorial change throughout the labeling.

If you have any questions, call Betsy Scroggs, Pharm. D., Consumer Safety Officer, at (301) 827-1250.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Robert Justice
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